

OCT 14 2011

**Section 16 – 510(k) Summary**

**Submitter:** MEDRAD, INC.  
One Medrad Drive  
Indianola, PA 15051

**Contact Person:** Mike Burnside  
Manager, Regulatory Affairs  
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**Date Prepared:** September 15, 2011

**Trade Name:** MEDRAD Mark 7 Arterion Injection System

**Classification:** II

**Product Code:** DXT

**Predicate Device(s):** The subject device is equivalent to the following devices:

- MEDRAD Mark V Provis Injection System (NFJ)
- K903390 MEDRAD Mark V Plus Injection System
- K050456 MEDRAD Avanta Fluid Management System

**Device Description:** The MEDRAD Arterion Mark 7 is a software controlled medical device used to inject contrast agents from a 150ml disposable syringe. Commonly referred to as a powered injector it is designed to allow a user to fill a disposable syringe, and perform an injection with a preprogrammed volume and flow rate. The Arterion consists of three basic components or modules: a Power Unit, Display Control Unit (DCU), and an injector head.

**Intended Use:** The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

**Comparison to predicate:** Design changes were made to the predicate device which included: newer technology for the display/user interface encompassing associated software changes or enhancements, architectural changes to the injector head (front load of the syringe), and modernization of the power supply. The device is lighter in weight and also has a smaller imprint for ease of placement and movement.

**Performance Data**

Bench and laboratory testing were performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use, and that its' intended use has not changed from the predicate. This included the following testing:

- Biocompatibility of Disposables (neat extracts)
  - Cytotoxicity (ISO 10993-5)
  - Intracutaneous Reactivity (ISO 10993-10)
  - Sensitization (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - Material Mediated Pyrogen (ISO 10993-11)
  - Physiochemical (ISO 10993-18)
  - Hemocompatibility
- Device Operational Characteristics
- Fluid Delivery Testing
- Human Factors Engineering
- Electrical Design Element Testing
- Mechanical Design Element Testing
- Software Verification/Validation

**Conclusion:**

MEDRAD considers the Mark 7 Arterion Injection System to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indication for use, fundamental technology, and principles of operation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

OCT 14 2011

Medrad, Inc.  
c/o Mr. Mike Burnside  
Manager, Regulatory Affairs  
One Medrad Drive  
Indianola, PA 15051

Re: K112086

Trade/Device Name: MEDRAD Mark 7 Arterion™ Injection System  
Regulation Number: 21 CFR 870.1650  
Regulation Name: Angiographic Injection Syringe  
Regulatory Class: Class II  
Product Code: DXT  
Dated: September 15, 2011  
Received: September 16, 2011

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations; Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

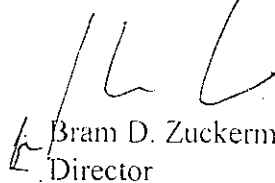
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(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director

Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112086

**Device Name:** MEDRAD Mark 7 Arterion™ Injection System

### Indications for Use:

The MEDRAD Mark 7 Arterion Injection System is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K112086